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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,144	07/13/2005	Juan Ramella	P70596US0	9818

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
03/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,144	RAMELLA, JUAN	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/9/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-22* is/are pending in the application.

4a) Of the above claim(s) *12-15* is/are withdrawn from consideration.

5)☒ Claim(s) *21* is/are allowed.

6)☒ Claim(s) *1,2,4,6-8,10,11,17-20 and 22* is/are rejected.

7)☒ Claim(s) *5,9 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/09 has been entered.

Response to Amendment

In the reply filed 2/9/09, applicant amended claims 1, 10, and 18, and added new claim 22. Claims 1, 2, and 4-22 are currently pending, and claims 1—15 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6, 7, 10, 11, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abel et al. (US 4,265,760) in view of Laffay (FR 2,766,797).

1. With respect to Claims 1, 2, 10, and 22, Abel et al. (hereafter 'Abel') teaches a filter apparatus for preparing a liquid solution comprising two outer sheets and a flexible inner sheet 105 that divides the interior of the bag into a first chamber 106 and second chamber 107 (see Figure 5). A powdered solute is disposed in the first chamber, such that it mixes with filtered, sterilized water such that the system of Abel is callable of creating a dialysis fluid for medical use (see Column 3, Lines 29-55; Column 1, Lines 61-68; and the embodiment of Figure 5). The inner sheet comprises a filter screen that extends prevents powdered solute from transferring into the second chamber. The two outer sheets and inner sheet are water-tightly joined at a periphery of the bag. Abel further discloses a fluid inlet 102 in communication with the first chamber 106 and a fluid outlet 103 in communication with the second chamber 107. Abel, however, does not specifically teach that the filter means of the inner sheet is disposed exclusively at the distal end of the bag (i.e. opposite side from the inlet), nor does Abel teach that the fluid inlet and outlet are disposed as a circular access bushing affixed to a side wall with the bag via a first and second aperture in the inner sheet and one of the outer sheets.

Regarding Abel's failure to specifically teach that the inner sheet's filter means is disposed exclusively at the distal end of the bag, it has been held that the omission of an element and its function is obvious when the function of the element is not desired. In this case, it would have been obvious to reconfigure the inner sheet of Abel such that the filter means is only disposed at the distal end of the chamber if transfer of fluid from the first chamber to the second chamber was only desired at the distal end of the device. See MPEP § 2144.04. II. A.

Regarding Abel's failure to specifically teach an annular bushing on a sidewall of the bag, Laffay teaches a medical bag for the preparation of dialysis solution comprising a bushing 8 built directly into the side wall of the bag. The bushing comprises first and second flow paths. Fluid enters the chamber through the first flow pat 22, where it is combined with powdered dialysis solution. The fluid mixes with the powder, forming dialysis fluid, and is removed from the chamber through the outlet tube 26. The outlet tube comprises a filtration element at its entrance, such that powder does not exit the bag. The bag and bushing, therefore, function in the same manner as claimed by applicant. It would have been obvious to one skilled in the art at the time of invention to modify the medical fluid dilution and filter apparatus of Abel with Laffay's dual-lumen bushing and use of a filter to block the flow of powdered solute in order to provide an alternate inlet/outlet means for creating a dialysis fluid from powdered solute. The use of a dual-lumen, annular bushing does not provide any functional advantage over the inlet and outlet of Abel, and the use of dual-lumen bushings on the sides of multi-chamber medical bags is well known in the art.

With respect to Claims 6, 7, and 11, Laffay clearly suggests the placement of an annular bushing with a fluid-tight fitting on the side of the bag, said bushing having two flow paths. It would have been obvious to one of ordinary skill in the art at the time of invention to rearrange the bushing of Laffay such that the second tube is a radial tube because doing so does not provide any additional functionality over the prior art. The bushing system of Laffay is fully capable of functioning identically to the claimed bushing.

2. Claims 4, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abel in view of Laffay, further in view of Mathieu (US 5,616,305).

3. With respect to Claim 4, Abel and Laffay disclose the medical fluid bag system of Claim 1 (see above rejection). Abel and Laffay, however, do not specifically teach that the powdered solute is sodium bicarbonate. Mathieu discloses a hemodialysis packaging unit comprising a layer of sodium bicarbonate powder 74 (Column 9, Lines 47-55). The use of sodium bicarbonate for dialysis treatment of blood is established in the art, especially when used in conjunction with powdered dialysis solution. Therefore, it would have been obvious to one skilled in the art at the time of invention to modify the system of Abel and Laffay with the layer of sodium bicarbonate of Mathieu in order to allow for an alternate, well-established means of creating dialysis fluid for medical treatment. Furthermore, Abel and Laffay both teach the placement of the layer of powdered solute before the filtering layer 28 in order to prevent undissolved particles from leaving the bag. Therefore, it would have been obvious to place the sodium bicarbonate before the filter (i.e. in the first chamber) of the device of Abel.

4. Claims 8 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abel in view of Laffay, and further in view of Verkaart et al. (US 2002/0030002). Abel and Laffay reasonably suggest the device substantially as claimed (see rejection above), but do not specifically teach a cover for sealing the entrance to the flow channels. Vekaart et al. (hereafter Vekaart) teaches a filter bag system comprising a

fluid inlet and a fluid outlet. The fluid outlet comprises a removable cover portion 226 that acts as a sealing valve, said valve being openable to provide fluid communication through the channel [0022]. The removable cover 226 prevents the contamination of the fluid line by external air prior attaching a conduit, thereby reducing the risk of infection of the blood. The step of providing a sealing means to the ends of a conduit to prevent contamination is well established in the art of medical fluid containers. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the device of Abel in view of Laffay with the tube sealing means of Vekaart in order to prevent fluids from entering the tube before it is connected to a blood source, thereby preventing infection.

Allowable Subject Matter

5. Claim 21 is allowed.

Claims 5, 9, and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The prior art teaches blood bag of Claim 1, but does not teach the layer attached to the second chamber and made from a woven or injected material, or the use of a valve comprising a thin sheet having a section having lesser strength lines that open

and close the valve. Verkaart teaches the use of a valve, but none of the prior art teaches a thin sheet disposed in the second chamber that acts as a valve.

Response to Arguments

6. Applicant's arguments with respect to claims 1, 2, 4-11, and 16-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
2 March 2009